UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. INNOVATIVE BIODEFENSE, INC., ET AL., Defendants.	No. 8:18 CV 996-DOC (JDE) **ORDER OF PERMANENT INJUNCTION**

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and the Court's inherent equitable authority, and personal jurisdiction over all parties. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

2. The Amended Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. (the "Act").

3. Defendants violate 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i).

4. The term "Defendants' Labeling" in this Order means labeling as defined in 21 U.S.C. § 321(m) and includes, but is not limited to, product labels, promotional materials, websites, social media pages, and any other media owned, operated, or controlled directly or indirectly by any of the Defendants or over which any of the Defendants has editorial control.

5. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them are permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly manufacturing, processing, packaging, labeling, holding, or distributing any new drugs, including but not limited to Zylast Broad Spectrum Antimicrobial Antiseptic, Zylast XP (Extended Protection) Antiseptic Lotion, Zylast XP (Extended Protection) Antiseptic Foaming Wash (collectively, "Zylast products"), or any product labeled similarly to such products, unless and until: (1) an approved new drug application ("NDA"), an abbreviated new drug application ("ANDA"), or an investigational new drug application ("IND") filed pursuant to 21 U.S.C. § 355 is in effect for such drug product(s); or (2) the following occur:

A. Defendants retain, at their expense, an independent person or person(s) (the "monograph expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to review the formulation of

Defendants' OTC drug products and Defendants' Labeling for such products to determine whether such products conform to an applicable final or tentative final OTC drug monograph and to other labeling requirements of the Act and its implementing regulations. Defendants shall notify FDA in writing of the identity and qualifications of the monograph expert as soon as they retain such expert;

B. Defendants remove from Defendants' Labeling all claims that do not conform to applicable final or tentative final OTC drug monographs relating to effectiveness against specific diseases or pathogens (such as, but not limited to, Methicillin-Resistant Staphylococcus Aureus ("MRSA"), Ebola, norovirus, diarrhea, rhinovirus, cold viruses, rotavirus, E. coli, H_1N_1, flu viruses, the stomach flu, HIV, Herpes viruses, or Vancomycin-resistant enterococci), including express or implied claims of effectiveness, extended efficacy claims, and infection reduction or prevention claims;

C. For each drug product that Defendants propose to directly or indirectly manufacture, process, pack, label, hold, or distribute, the monograph expert performs a comprehensive review of the product's formulation and Defendants' Labeling for such product, to determine whether the product: (i) conforms to an applicable final or tentative final OTC drug monograph; (ii) conforms to all labeling requirements, including 21 C.F.R. Part 201, and (iii) is not otherwise misbranded;

D. For each drug product the monograph expert reviews pursuant to paragraph 5(C), Defendants ensure that the monograph expert certifies in writing to FDA that:

(i) the monograph expert has reviewed the proposed OTC drug product, its formulation, and Defendants' Labeling for such product;

(ii) the proposed OTC drug product's formulation and Defendants' Labeling for such product conform to an applicable final or tentative final OTC drug monograph and to all applicable labeling requirements, including 21 C.F.R. Part 201. If

a tentative final OTC monograph subsequently becomes final and effective, it may be necessary to reformulate and/or relabel such a product to conform to its requirements, or, in the alternative, to seek FDA approval of a new drug application under 21 U.S.C. § 355; and

(iii) the drug is not otherwise misbranded.

As part of this certification, the monograph expert shall attach Defendants' Labeling that was reviewed and provide a detailed and complete report of the results of the monograph expert's labeling review, including references to the applicable final or tentative final OTC drug monograph and labeling regulations consulted by the monograph expert in conducting the review;

E. Defendants have provided FDA with any additional information requested by the agency to review the monograph expert's certification or Defendants' compliance with this Order, the Act, and its implementing regulations; and

F. FDA notifies Defendants in writing that they appear to be in compliance with the terms set forth in paragraphs 5(A)-(E) of this Order. In no circumstances may FDA's silence be construed as a substitute for written notification.

6. After Defendants have either an NDA, ANDA, or IND under 21 U.S.C. § 355 in effect for its drug product(s) or Defendants have complied with paragraphs 5(A)-(E) and received written notification from FDA pursuant to paragraph 5(F), Defendants shall select and retain, at Defendants' expense, an independent person or persons who shall meet the criteria described in paragraph 5(A) (the "Auditor"). Once Defendants receive the notification pursuant to paragraph 5(F), the Auditor shall conduct audit reviews of Defendants' products' formulations and Defendants' Labeling not less than once every six (6) months for a period of one (1) year, and then not less than once a year for the following two (2) years, for a total of three (3) years. The first audit shall occur not more than six (6) months after Defendants have received the written notification from FDA pursuant to paragraph 5(F). If Defendants choose, the Auditor

may be the same person or persons retained as the monograph expert described in paragraph 5(A).

A. At the conclusion of each audit review, the Auditor shall prepare a detailed written audit report ("Audit Report") that analyzes whether Defendants are in compliance with the FDCA's new drug provisions or with an applicable final or tentative final OTC drug monograph, as well as other labeling requirements of the Act and its implementing regulations, and identifies any deviations from such requirements ("Audit Report Observations").

B. Each Audit Report shall contain a written certification that the Auditor: (a) has personally reviewed for each of Defendants' products, the product's formulation and Defendants' Labeling for such product; and (b) personally certifies whether the product's formulation and Defendants' Labeling are in compliance with this Order, the Act, and its implementing regulations.

C. As a part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA, at the address provided in paragraph 17, no later than fifteen (15) business days after the date the audit review is completed. In addition, Defendants shall maintain their Audit Reports and shall promptly make the Audit Reports available to FDA upon request.

D. If an Audit Report contains any observations indicating that Defendants are not in compliance with this Order, the Act, or its implementing regulations, Defendants shall, within fifteen (15) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations may take longer than fifteen (15) calendar days, Defendants shall, within ten (10) calendar days after receipt of the Audit Report, submit to FDA in

writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance, shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule.

E. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within thirty (30) calendar days after the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

7. Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, are permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction or causing the introduction or delivery for introduction into interstate commerce any drug that is a new drug within the meaning of 21 U.S.C. § 321(p) and that is not approved under 21 U.S.C. § 355(b) or (j), exempt from approval under 21 U.S.C. § 355(i), or does not conform strictly with each of the conditions of an applicable final or tentative final OTC drug monograph; and

B. Any act that results in the failure to implement and continuously maintain the requirements of this Order.

8. FDA shall be permitted, without prior notice and when FDA deems necessary, to inspect Defendants' place(s) of business and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with this Order, the Act, and its implementing regulations. During inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, Defendants' products' formulations, Defendants' Labeling, and other materials therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, Defendants' Labeling, and other materials; and to examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all drugs and their respective components. The inspection authority granted by this Order is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

9. Upon entry of this Order, if at any time FDA determines, based on the results of an inspection, the analysis of a sample, a report, or any other information, that Defendants have failed to comply with any provision of this Order, have violated the Act or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Order, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease directly or indirectly manufacturing, processing, preparing, packing, labeling, holding, selling, and/or distributing any or all drugs;

B. Recall, at Defendants' expense, any drug products that are unapproved or otherwise in violation of this Order, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Order;

D. Submit additional reports or information to FDA as requested;

E. Issue a safety alert; or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Order, the Act, and its implementing regulations, including reinstituting any of the measures set forth in paragraph 5(A)-(E) of this Order.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA under this Order or the law.

10. Upon receipt of any order issued by FDA pursuant to paragraph 9, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 9 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA's inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in paragraph 9 shall be borne by Defendants at the rates specified in paragraph 11.

11. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Order, including the travel incurred by specialized investigatory and expert personnel, at the standard rates prevailing at the time the costs are incurred. As of the date of this Order, these rates are: $101.00 per hour or fraction thereof per representative for inspection work; $121.06 per hour or fraction thereof per representative for analytical or review work; $0.575 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the

inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

12. Within ten (10) business days after entry of this Order, Defendants shall post a copy of this Order in a common area at Defendants' place(s) of business and any other location at which Defendants conduct business and/or directly or indirectly manufacture, process, pack, label, hold, or distribute any drugs, and shall ensure that the Order remains posted for as long as the Order remains in effect.

13. Within ten (10) business days after entry of this Order, Defendants shall provide a copy of the Order by personal service or certified mail (restricted delivery, return receipt requested) to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, including but not limited to Zylast Direct and Westwood Laboratories, Inc. (collectively referred to as "Associated Persons"). Within twenty (20) business days after entry of this Order, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Order.

14. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Order, Defendants immediately shall provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time any Defendant becomes associated with an additional Associated Person(s), it shall, within ten (10) business days, provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Order pursuant to this paragraph.

Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

15. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of their business that occurs after entry of this Order, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Innovative BioDefense or Zylast Direct or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Order. Defendants shall provide a copy of this Order to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

16. All decisions specified in this Order shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A), if necessary. Review by a court of any FDA decision rendered pursuant to this Order shall be based exclusively upon the written record before FDA at the time of the decision. No discovery shall be taken by any party.

17. All notifications, correspondence, and communications to FDA required by the terms of this Order shall reference the case name and civil action number, be prominently marked "Permanent Injunction Correspondence" and "Innovative BioDefense" and be mailed to District Director, Los Angeles District Office, Pacific Region, U.S. Food and Drug Administration, Department of Health and Human Services, 19701 Fairchild, Irvine, CA 92612-2508 and sent electronically to ORAPHARM4_Responses@FDA.HHS.GOV.

18. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and court costs or any other fees relating to such contempt proceedings.

19. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED.

Dated: May 4, 2020

David O. Carter
United States District Judge